

Creative and Novel Ideas in HIV Research Request for Concept Proposals

Purpose

The purpose of the Creative and Novel Ideas in Research Awards Program (CNIHR) is to create a mechanism via the established Centers for AIDS Research (CFARs) to fund developmental projects to bring insight and new ideas from early stage investigators, some of whom will have expertise in other disciplines, to the HIV/AIDS field of study. The intent of this program is to attract both international and U.S.-based young, early stage investigators from outside the field of HIV/AIDS research to help address new questions related to emerging issues of long-term survival with HIV infection, and the prevention of HIV transmission.

Eligibility

Early stage investigators (i.e., who have received their doctoral degree within the last ten years) who are faculty in good standing at an academic institution or have a comparable position in an institution whose primary mission is research are eligible. If currently completing post-doctoral training, the applicant must have completed their training and have a faculty or comparable position prior to concept proposal submission deadline of December 22, 2009. Investigators from such disciplines as (but not limited to) Molecular and Cellular Biology, Immunology, Virology, Pharmacology, Genomics/Genetics/Gene Technology, Structural Biology, Chemistry/Biochemistry, Infectious Disease, Biotechnology, Behavioral and Social Sciences, Oncology, Metabolic Research, Cardiovascular Research, Neurology, Public Health, Health Services Research, Epidemiology, Pathology, Bioengineering, Implementation Science/Operations Research; who have not previously conducted HIV/AIDS research are encouraged to apply.

Researchers who have had any previous grant, contract, sub-award or publication in HIV/AIDS research are not eligible. Applicants may be located at one of the CFAR sites or may be external to those sites. Applicants from all countries (unless excluded because of regulations applicable to embargoed countries – see link: http://www.treas.gov/offices/enforcement/ofac/programs/) are encouraged to apply. Eligible Principal Investigators (PIs) include: Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support.

Types of Projects

Research topics could include any aspect of science, but should not include clinical trials of new drugs, treatments, or devices; or off-label use of a licensed drug. If an applicant is considering a study involving approved drugs and/or standard-of-care, the applicant will be encouraged to contact the review administrator to determine whether the proposed project would be eligible for funding.

Funding Available

Awards will be funded for 1-2 years, up to \$150,000 (direct costs) per year plus applicable indirect costs. Additional support will be provided for grantees to attend the XVIII International AIDS Conference in Vienna in July 2010 and the VI IAS Conference on HIV Pathogenesis, Treatment, and Prevention in Rome in July 2011, depending on their award period. Award funds may be used for salary, technical support, laboratory supplies, equipment, or travel to a scientific conference or other training activity. Funds may not be used to offset losses of funding incurred through nonrenewal of grant funds or through decreases in grant funds due to across-the-board cuts. We anticipate making 6-12 awards.

Requests for Second Year Funding: Second year funding is contingent upon demonstration of satisfactory progress during year one.

Application Process and Instructions

The competition will be administered in a two-phase process, the Concept Proposal phase, and the Full Proposal phase. To be eligible to compete in the full proposal phase, the applicant must first successfully compete in the Concept Proposal phase.

The Concept Proposal should include a cover letter, an NIH-style biosketch (http://grants.nih.gov/grants/funding/phs398/biosketchsample.pdf), a budget, and a two-page proposal outlining the hypotheses, specific aims, brief preliminary data (if any), and brief research design. The Concept Proposal is submitted electronically in one MS Word or Adobe PDF file via the CNIHR website (www.cnihr.org).

The Concept Proposals will be reviewed by a Scientific Review Committee (SRC). Criteria for selection in the Concept Proposal phase are primarily based upon relevance of the proposal to understanding and impacting the HIV field of study. Researchers whose proposals are selected for the full proposal competition phase will be notified and have eight weeks to prepare and submit a full proposal. The proposal will follow a modified NIH investigator initiated grant application (R01) format (http://www.niaid.nih.gov/ncn/grants/app/default.htm) and be limited to 10 pages. Awardees will also be eligible for and encouraged to access CFAR Core services (from collaborating CFAR) like any other Developmental Award applicant. For more information about CFARs and CFAR Core services, see the NIH CFAR website (http://www3.niaid.nih.gov/LabsAndResources/resources/cfar/).

Applicants who are chosen to submit a full proposal and do not already have a relationship with a CFAR will be required to establish a mentor/collaborator relationship with a CFAR-affiliated investigator. Resources regarding potential CFAR-affiliated mentor/collaborators are provided on the CNIHR website (www.cnihr.org), including a link to the NIH CFAR webpage describing which CFARs are collaborating with international institutions, and a list of potential CFAR mentor/collaborators describing their expertise and contact information. Applicants who are unable to find a mentor/collaborator through these resources are encouraged to contact the CNIHR program at info@cnihr.org.

Review Process and Criteria

Each application will be assigned a primary and secondary reviewer from the SRC. The evaluation criteria for full proposals include:

- <u>Scientific Merit</u> of the proposal and its likelihood to provide information that can significantly advance our understanding of HIV and/or provide preliminary data that is likely to lead to independent research grant funding.
- <u>Significance</u> Does the study address an important problem consistent with the objective to advance our understanding of HIV? If the aims are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive the field of HIV and AIDS?
- <u>Approach</u> Are the conceptual framework, design methods, and analyses adequately developed, well integrated and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternatives?
- <u>Innovation</u> Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- <u>Environment</u> Does the proposed methodology take advantage of the unique environment and unique populations where appropriate? Are useful collaborative arrangements between resources in the institution(s) utilized where appropriate and described adequately?

The reviewers are asked to summarize the strengths and weaknesses of the proposal based on all of the above criteria. The SRC will convene a formal review and priority scoring within six weeks of receipt of applications. Each project is scored according to the NIH scoring system using both scientific merit and relevance to the center's partnership as a metric for success. Those projects that are selected for funding will be notified immediately. Applicants will receive written critiques in order to enhance their ability to benefit from opportunities from other funding sources.

Pre-Award Requirements

<u>Human Subjects and Animal Care Approvals</u>: Animal Care and Institutional Review Board approvals, if applicable, <u>must be obtained prior to **receipt** of an award</u>, but are not required to submit an application. Proposals involving either international sites or clinical research above minimal risk will require additional clearance from NIH prior to receipt of an award, which includes IRB approval from all participating sites and human subjects training certification for all key personnel. For more information about human subjects approval, see: http://www.hhs.gov/ohrp/. For more information on animal care approvals, see: http://grants.nih.gov/grants/olaw/olaw.htm.

Post-Award Requirements

- 1. Prior to funding, a copy of all Institutional Biohazard, Animal Care and IRB approvals must be forwarded to the UAB CFAR Administrative Director. If the project involves human subjects and the institutional IRB has deemed the study "greater than minimal risk", the awardee must submit a Clinical Research Checklist to the CFAR Administrative Director before funding is released. For more information on the definition of minimal risk, see: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102. If the project is being conducted at a non-U.S. site, prior approval from NIH is required prior to commencement of the study. It is recommended that if your study is minimal risk or below, you apply for independent approval by the applicable IRB this would avoid the need to get additional approval from NIH for domestic studies.
- 2. To ensure that the awardee and mentor/collaborator have a clear understanding of their roles, responsibilities, and research goals, each awardee and mentor/collaborator will be asked to develop a brief written agreement that describes the following: 1) Expectations for the mentoring/collaborative experience; 2) Expectations regarding the time and frequency of meetings; 3) Timetable for the project; and 4) Expectations about collaboration on this project (i.e., authorship on presentations and publications).
- 3. Awardees will be required to submit yearly progress reports to the UAB CFAR and make an oral presentation at either the annual International AIDS Conference or an International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention meeting, or the annual CFAR Research Symposium.
- 4. CFAR and CNIHR support must be acknowledged in all publications derived from the CNIHR award.
- 5. In the event that other pending support is funded which overlaps with or reduces the principal investigator's effort on this project, the PI must notify the UAB CFAR Administrative Director. CNIHR awardee's funding status will be reviewed and if it is determined that the PI is unable to meet the specific aims of the proposal, the CNIHR award will be revoked.
- 6. After project is completed, the CNIHR awardee is required to be available to provide information about publications, collaborations, and future grants related to the CNIHR project.

Table 1 below describes the timeline for the CNIHR funding program.

	2009		2010							
	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	July	Aug
Call for Concept Proposals	16									
Concept Sheets Due		22								
Concept Sheet Review				5						
Call for Full Proposals				22						
Full Proposals Due						22				
Proposals sent to reviewers						23-	-20			
Review Mtg/Awardees Selected								4		
Awardees announced at IAS									18	
Subcontracts made to Awardees									19	
Awardees begin projects										6

Types of Eligible Institutions

U.S.-based Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Research Institutes
- Hispanic-serving Institutions whose primary focus is research
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions whose primary focus is research
- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education) whose primary focus is research
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education) whose primary focus is research
- Small Businesses whose primary focus is research
- · For-Profit Organizations (Other than Small Businesses) whose primary focus is research
- Regional Organizations whose primary focus is research

Non-U.S.-based Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Research Institutes
- Nonprofit Organizations whose primary focus is research
- · Nonprofit Organizations whose primary focus is research
- Small Businesses whose primary focus is research
- For-Profit Organizations (Other than Small Businesses) whose primary focus is research
- Regional Organizations whose primary focus is research

If unsure about your eligibility, go to the CNIHR website (www.cnihr.org) for more information.